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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/980,400	11/26/97	SLEDZIEWSKI A	13952A-00532

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TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER	
KAUFMAN, C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 09/28/98

#6

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 08/980,400	Applicant(s) Sledziewski et al.
	Examiner Claire M. Kaufman	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Nov 26, 1997* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *29-58* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *29-58* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *29-58* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The preliminary amendment filed Nov. 26, 1997 has been entered.

2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

Information Disclosure Statement

3. The IDS submitted November 26, 1997 has been considered. The parent applications containing references cited were missing 3 references at the time the current application was examined. Accordingly, references BD (Ellis et al.) , CK (Struhl et al.), and CL (Broach et al.) were not consideration. Applicants may, in response to this action, submit copies of any references listed on the PTO 1449 which have not been considered. No fee or additional PTO 1449 is required with such a submission as it will be considered to have been part of the original IDS submitted prior to the first action on the merits.

Claim Objections

4. Claim 39 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Because the multimerized polypeptide of claim 37 must have an immunoglobulin heavy chain constant region, dependent claim 39 which repeats this requirement does not further limit claim 37.

5. Claim 36 is objected to because of the following informality: "the dimerized protein one of" should add an --of-- before "one". Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 29-36, 45-53 and 55-57 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 5, 750,375 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:1) a secreted PDGF receptor analog which is a dimerized or multimerized polypeptide fusion comprising a first non-immunoglobulin polypeptide (*i.e.*, PDGF receptor or its ligand binding domain) joined to a first immunoglobulin constant region (either a heavy or light chain), and a second non-immunoglobulin polypeptide fused to a second immunoglobulin constant region; and 2) a heteromultimeric polypeptide fusion comprising a first receptor domain requiring multimerization for activity joined to a first immunoglobulin constant domain region, and a second polypeptide fusion comprising a second receptor domain requiring multimerization for activity jointed to a second immunoglobulin constant region (see patented claim 9 and current claims 56 and 57, especially).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application

which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

7. Claims 29-31, 35, and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5, 155,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because the currently claimed dimerized polypeptide fusion cannot be produced by a means significantly different from the method of the patented claim, and the patenting of the method puts the claimed polypeptide in the hands of those who can practice the method.

8. Claims 29-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 08/475,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because the currently claimed dimerized, multimerized, and heteromultimerized polypeptide fusions cannot be produced by a means other than the method of the patented claim, and the patenting of the method puts the claimed polypeptide in the hands of those who can practice the method. In the instance where the patented claims are drawn to methods of producing species of polypeptide fusions, since the species are encompassed by the genuses of the pending polypeptides, the method of producing the species renders the genus obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, once this application issues as a patent, this rejection will no longer be provisional.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 45 and 46 and dependent claims 47-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is indefinite because in lines 5 and 6, respectively, it recites the amino acid sequence of "Figures 1A-1D (Sequence ID Numbers 1 and 2)" and "Figures 11A-11D (Sequence ID Numbers 35 and 36)". However, SEQ ID NO:1 and 35 are a nucleic acid sequence and Figures 1A-D and 11A-D shown nucleic acid sequences. Since the claim is drawn to amino acid sequences, the rejection could be obviated by not referring to the Figures and nucleic acids, but instead referring to SEQ ID NO:2 and SEQ ID NO:36, respectively.

Claim 45 is indefinite because it is drawn to a "heteromultimeric polypeptide fusion", but the claim does not specify what part(s) of the fusion makes the polypeptide a hetero- instead of homomultimer. That is, it is unclear if the different parts are the non-Ig (immunoglobulin) polypeptides or the multimerizing protein. As a result, the invention is not distinctly claimed.

10. Claims 37 and 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: multimerized elements. The claim is drawn to "a multimerized polypeptide fusion", but does not contain components which form a multimerizing polypeptide fusion. The only components are a non-Ig polypeptide fused to an Ig C_L (light chain constant region), and an Ig C_H (heavy chain constant region). Put together, these do not form a multimerizing polypeptide fusion because nothing multimerizes with the non-Ig polypeptide.

11. Claims 29-58 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that the claims fail to correspond in scope with that which applicant(s) regard as the invention can be found in the specification and original claims. In the Disclosure of the Invention on pages 5-12 and original claims, applicant has stated that the invention is drawn to a *secreted, biologically active* dimerized or multimerized polypeptide fusion (emphasis added), and this statement indicates that the invention is different from what is defined in the claim(s) because the instant claims do not recite that the polypeptide fusion is both secreted and biologically active.

Priority

12. Application 07/347,291, filed 05/02/89, does not appear to disclose the concept of multimerized or heteromultimerized polypeptide fusions as currently claimed, so that priority for this aspect of the present invention has the priority date of application 07/634,510, filed 12/27/90.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claim 37-45, 47-55 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Capon et al. (AG).

Capon et al. teach a multimerized polypeptide fusion comprising a ligand binding protein ("A") joined to an Ig C_L and an Ig C_H (col. 10, lines 40-53; col. 12, lines 22-29). Also taught is that the constant regions are from IgG-1, -2, -3, or -4 (also called Igγ in the art; col. 14, lines 65-67). In col. 11, heterotetramers are described in which four polypeptide fusions each having a non-Ig polypeptide ("A") joined to an Ig multimerizing protein. There is also a description of inclusion of a hinge region joined to the Ig C_H region in col. 10, lines 10-15: "Typically, such

fusions retain at least functionally active hinge, CH2 and CH3 domains of the constant region of an immunoglobulin heavy chain." Capon et al. further teach joining of an Ig variable region to the Ig C_H region (col. 12). While the type of variable regions are not discussed, variable regions only exist in the form of V_H, Vκ, and Vγ, therefore, one of these types would necessary have been used. Heteromultimeric polypeptides like those described above are also illustrated in col. 13, line 20, through col. 14, line 22, these include cases in which the first and second immunoglobulin constant regions are different (*e.g.*, C_L and C_H)

Prior Art

14. It is noted that Capon et al. (AG) do not teach a heteromultimeric polypeptide fusion in which the non-Ig polypeptides are a receptor or receptor domain requiring multimerization for activity (including PDGF receptor).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

cmk
September 24, 1998

LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP 1800